Butler, Jennie C

From: David C. Steinberg [DavidPreserve@home.com]
Sent: Tuesday, May 09, 2000 9:37 AM
To: FDADockets@oc.fda.gov
Subject: Participation at 6/28 Meeting

To: Dockets Management Branch of the FDA

Subject: Request to attend and speak at the Public Hearing on Regulation of OTC Products June 28,29,2000

From: David C. Steinberg, President Steinberg & Associates, Inc.

Dear Sirs:

I would like to address the FDA on this subject. I will briefly discuss the success of the OTC Monograph system for making it easy for manufacturers to offer safe and effective OTC drugs to consumers. This is especially true for topically applied drugs without dose restrictions. These drugs are commonly called cosmetic drugs. There is one major drawback to the system, which needs improvement. There is a need for a simple transparent system to allow new actives to be added to Monographs without the costly and time-consuming current NDA route.

The FDA was criticized at the Mutual Understanding 2000 Conference held in Malta in April of this year, on Global Harmonization of Regulations, as being "old fashion" and out of step with the rest of the world's cosmetic/drug regulatory mechanisms. Most speakers praised the EU system. However, the EU system didn't really start to approve new ingredients, which are regulated in the US as OTC drug actives, until they made their approval system transparent. They published a list of safety testing required for "actives" so raw material suppliers could than run the tests and if found to be safe by a committee of independent experts, the new ingredient could than be approved for use.

Since the Monograph system started, we have had only 1 new UV filter added to the Monograph, and no new antiperspirant, anti-microbial, skin protectants, anti-dandruff, etc. drugs approved! We have stifled innovation. As the Monographs clearly define efficacy-testing requirements, the only issue is how and what safety data should be required for submission and a mechanism to quickly review and approve new actives.

Thank you,

David C. Steinberg

Steinberg & Associates, Inc. 16 Mershon Lane Plainsboro, NJ 08536

phone 1-609-799-1575, Fax 1-609-799-5271, E-mail davidpreserve@home .com

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